UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALFONSO PINALES, on behalf of himself and all others similarly situated, Plaintiff, v. SANOFI S.A., SANOFI-AVENTIS U.S. LLC, and SANOFI US SERVICES INC., Defendants.	Civil Action No. **CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff Alfonso Pinales ("Plaintiff") brings this action on behalf of himself and all others similarly situated against Defendants Sanofi S.A., Sanofi-Aventis U.S. LLC ("Sanofi-Aventis") and Sanofi US Services Inc. ("Sanofi Services") (collectively, "Sanofi" or "Defendants"). Plaintiff makes the following allegations pursuant to the investigation of his counsel and based upon information and belief, except as to the allegations specifically pertaining to himself, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit regarding Defendants' manufacturing, distribution, and sale of ranitidine-based over-the-counter medications under the brand name Zantac that contain dangerously high levels of N-nitrosodimethylamine ("NDMA"), a carcinogenic and liver-damaging impurity.

2. Zantac is an over-the-counter medication that contains ranitidine, which decreases the amount of acid created by the stomach. Over-the-counter Zantac is used for the treatment of heartburn associated with indigestion and sour stomach. However, Sanofi's manufacturing process has caused Zantac to contain dangerously high levels of NDMA.

3. NDMA is a semivolatile organic chemical. According to the U.S. Environmental Protection Agency, NDMA "is a member of N-ni-trosamines, a family of potent carcinogens." While NDMA is not currently produced in the United States other than for research purposes, it was formerly used "in production of liquid rocket fuel," among other uses. NDMA is listed as a "priority toxic pollutant" in federal regulations. *See* 40 CFR § 131.36. Exposure to NDMA can cause liver damage and cancer in humans. NDMA is classified as a probable human carcinogen, and animal studies have shown that "exposure to NDMA has caused tumors primarily of the liver, respiratory tract, kidney and blood vessels."

4. On September 13, 2019, the FDA issued a statement announcing the presence of NDMA in ranitidine medications, including Zantac.[1] The FDA's notice states that "NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests." Since then, the FDA's own testing "has found unacceptable levels of NDMA in samples of ranitidine."[2]

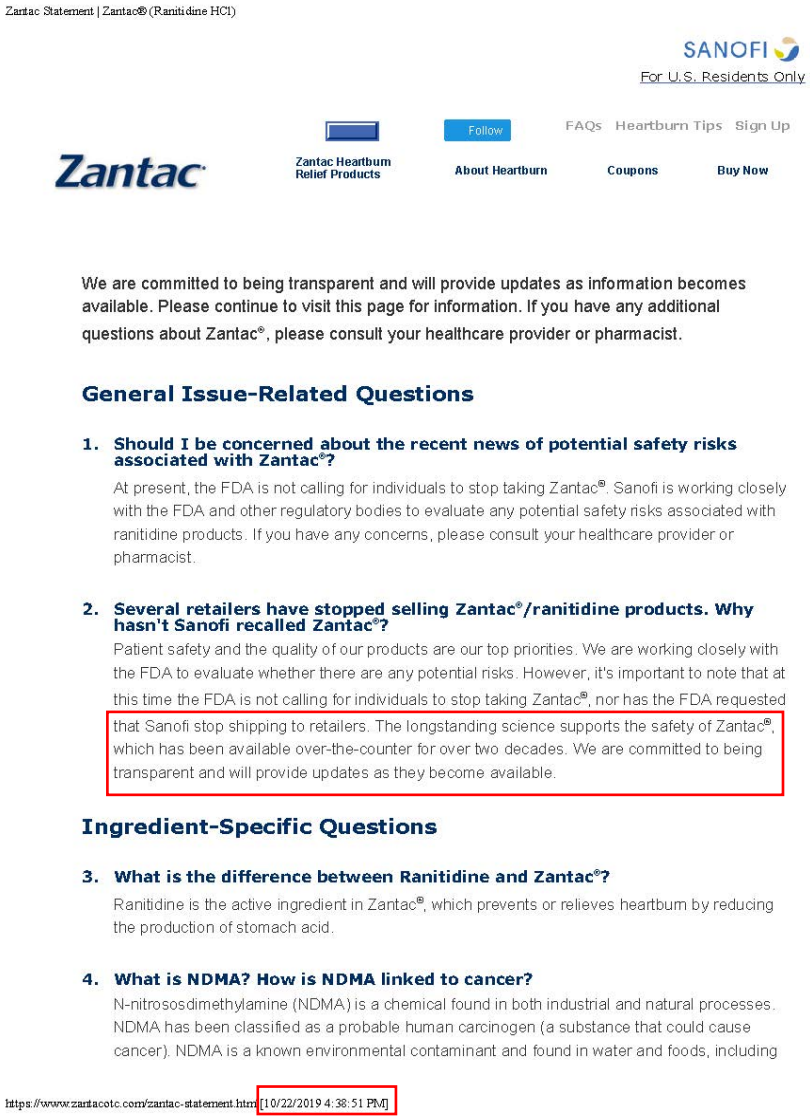
5. Several pharmaceutical manufacturers have issued recalls or halted the sale of their ranitidine medications. Pharmacies such as Walgreens, Rite Aid, and CVS have also ceased selling ranitidine medications.

6. On October 18, 2019, Sanofi issued a voluntary recall of Zantac "due to

[1] Food & Drug Admin., Statement Alerting Patients and Health Care Professionals of NDMA Found in Samples of Ranitidine (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine.

[2] Food & Drug Admin., 10/2/19: UPDATE – FDA Provides Update on Testing of Ranitidine for NDMA Impurities (Oct. 2, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

inconsistencies in preliminary test results" of the active ingredient in Zantac.[3] Despite this, Sanofi's recall notice on the Zantac website continues to direct consumers to a separate, pre-recall notice by Sanofi touting the safety of Zantac. Specifically, the notice states: "The longstanding science supports the safety of Zantac, which has been available over-the-counter for over two decades."[4]



Zantac Statement | Zantac® (Ranitidine HCl)

SANOFI
For U.S. Residents Only

Zantac

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We are committed to being transparent and will provide updates as information becomes available. Please continue to visit this page for information. If you have any additional questions about Zantac®, please consult your healthcare provider or pharmacist.

General Issue-Related Questions

1. **Should I be concerned about the recent news of potential safety risks associated with Zantac®?**
   At present, the FDA is not calling for individuals to stop taking Zantac®. Sanofi is working closely with the FDA and other regulatory bodies to evaluate any potential safety risks associated with ranitidine products. If you have any concerns, please consult your healthcare provider or pharmacist.

2. **Several retailers have stopped selling Zantac®/ranitidine products. Why hasn't Sanofi recalled Zantac®?**
   Patient safety and the quality of our products are our top priorities. We are working closely with the FDA to evaluate whether there are any potential risks. However, it's important to note that at this time the FDA is not calling for individuals to stop taking Zantac®, nor has the FDA requested that Sanofi stop shipping to retailers. The longstanding science supports the safety of Zantac®, which has been available over-the-counter for over two decades. We are committed to being transparent and will provide updates as they become available.

Ingredient-Specific Questions

3. **What is the difference between Ranitidine and Zantac®?**
   Ranitidine is the active ingredient in Zantac®, which prevents or relieves heartburn by reducing the production of stomach acid.

4. **What is NDMA? How is NDMA linked to cancer?**
   N-nitrosodimethylamine (NDMA) is a chemical found in both industrial and natural processes. NDMA has been classified as a probable human carcinogen (a substance that could cause cancer). NDMA is a known environmental contaminant and found in water and foods, including

https://www.zantacotc.com/zantac-statement.htm[10/22/2019 4:38:51 PM]

[3] Jen Christensen, *Sanofi Recalls Popular Heartburn Medication Zantac OTC*, CNN, Oct. 18, 2019, https://www.cnn.com/2019/10/18/health/zantac-otc-recall/index.html (last visited Oct. 22, 2019).

[4] ZANTAC STATEMENT, https://www.zantacotc.com (last visited Oct. 22, 2019) (click "Read More" on "A Message From Sanofi").

7. However, these representations are false, as Defendants' Zantac medication contains the carcinogenic impurity NDMA.

A. Zantac Is Marketed As Safe

8. Sanofi has always marketed Zantac as a safe and effective product, and has continued to do so despite the recent recalls of ranitidine medications.

9. Zantac is one of the most successful drugs in history. It reached $1 billion in sales in December 1986.[5]

10. On Zantac's website, Sanofi writes Zantac is "[c]linically proven to relieve heartburn in as little as 30 minutes."[6]

11. Sanofi also assures consumers it is safe to "take up to two (2) Zantac tablets a day."[7]

B. Zantac Contains Dangerous Levels Of NDMA

12. Contrary to the above assertions, Zantac contains dangerously high levels of NDMA that would not be present if the medication were properly synthesized. As noted in paragraph 4, *supra*, the FDA has found unacceptable levels of NDMA in samples of ranitidine.

13. The Medicines and Healthcare Products Regulatory Agency of the United Kingdom also issued an alert regarding Zantac, noting recalls issued by companies are "a precautionary measure due to possible contamination of the active substance in Zantac,

[5] Richard Wright, *How Zantac Became the Best-Selling Drug in History*, 16 J. OF HEALTHCARE MARKETING 24, 27 (1996).
[6] MAXIMUM STRENGTH ZANTAC 150, https://www.zantacotc.com/zantac-maximum-strength.html#learn-more (last visited Oct. 22, 2019).
[7] *Id*.

ranitidine, with an impurity called NDMA."[8] "The MHPRA has asked manufacturers to quarantine all ranitidine products which may contain the active pharmaceutical ingredient that is potentially affected by this issue."[9]

14. In the case of Zantac and other ranitidine medications, the cause of the NDMA contamination is still being investigated by the FDA and other regulatory agencies. However, the Health Products Regulatory Authority of Ireland, in issuing a recall of Zantac, has stated, "The reason for the recall is that a nitrosamine impurity has been identified in ranitidine active substance batches manufactured at a manufacturing site in India."[10]

15. The FDA has established a "permissible daily intake limit for…NDMA of 96 [nanograms]."[11] But Zantac has an NDMA content of between 2.5-2.8 million nanograms *per tablet*, according to testing by Valisure, an FDA-registered online pharmacy.[12]

150 mg Tablets or equivalent	**Lot #**	**NDMA per tablet (ng)**
Reference Powder	125619	2,472,531
Zantac, Brand OTC	**18M498M**	**2,511,469**
Zantac (mint), Brand OTC	**18H546**	**2,834,798**
Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, CVS	9BE2773	2,520,311
Zantac (mint), CVS	9AE2864	3,267,968
Ranitidine, Equate	9BE2772	2,479,872

[8] Medicine and Healthcare Regulatory Agency, Zantac – MHRA Drug Alert Issued as GlaxoSmithKline Recalls all Unexpired Stock (Oct. 8, 2019), https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock.

[9] *Id*.

[10] Health Products Regulatory Authority, Precautionary Pharmacy and Retail Level Recall of Several Batches of a Number of Ranitidine Medicines in Ireland (Sept. 23, 2019), https://www.hpra.ie/homepage/medicines/safety-notices/item?t=/precautionary-pharmacy-and-retail-level-recall-of-several-batches-of-a-number-of-ranitidine-medicines-in-ireland&id=d26b0c26-9782-6eee-9b55-ff00008c97d0.

[11] VALISURE, VALISURE CITIZEN PETITION ON RANITIDINE 1 (2019), https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf (last visited Oct. 22, 2019) (hereinafter "VALISURE PETITION").

[12] *Id*. at 6.

Ranitidine (mint), Equate	8ME2642	2,805,259
Ranitidine, Strides	77024060A	2,951,649

16. Furthermore, a 2016 study by Stanford University found that individuals who took Zantac had "NDMA levels [in their urine] more than 400 times greater than what the FDA considers acceptable."[13]

C. Plaintiff Was Harmed By Purchasing And Consuming Defective Zantac Manufactured By Defendants.

17. Plaintiff and the Class were injured by the full purchase price of their Zantac medications. These medications are worthless, as they contain harmful levels of NDMA. As the medications expose users to NDMA well above the legal limit, the medications are not fit for human consumption. Plaintiff is further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely-toxic NDMA, and for damages related to Defendants' conduct.

18. Plaintiff brings this action on behalf of the Class for equitable relief and to recover damages and restitution for: (i) breach of express warranty, (ii) breach of the implied warranty of merchantability, (iii) violation of New York's General Business Law § 349, (iv) violation of New York's General Business Law § 350, (v) unjust enrichment, (vi) fraudulent concealment, (vii) fraud, and (viii) conversion.

PARTIES

19. Plaintiff Alfonso Pinales is a citizen of New York who resides in Bronx, New York. During all relevant time periods, Mr. Pinales purchased and consumed Zantac manufactured by Defendants. Mr. Pinales originally learned about the Zantac defect when he

[13] Jonathan Lapook, *Potentially Dangerous Chemical Found in Popular Heartburn Pill Zantac*, CBS NEWS, Oct. 8, 2019, https://www.cbsnews.com/news/zantac-ndma-levels-potentially-dangerous-chemical-zantac-ranitidine-heartburn-pills-2019-10-08/.

saw a news story on ABC News. Further investigation revealed that Mr. Pinales has been using the defective Zantac manufactured by Sanofi for some time. When purchasing Zantac from Defendants, Mr. Pinales reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were properly manufactured, free from defects, and safe for their intended use. Mr. Pinales relied on these representations and warranties in deciding to purchase Zantac from Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased Zantac from Defendants if he had known that they were not, in fact, properly manufactured and free from defects. Mr. Pinales also understood that each purchase involved a direct transaction between himself and Sanofi because his medication came with packaging and other materials prepared by Sanofi, including representations and warranties that his medications were properly manufactured and free from defects.

20. Defendant Sanofi S.A. is a French corporation with a principal place of business at 54, Rue La Boétie, 75008 Paris, France. Sanofi S.A conducts substantial business in the United States, and specifically in the State of New Jersey and the State of New York. Sanofi S.A has been engaged in the manufacturing, distribution, and sale of defective Zantac in the United States, including in the States of New Jersey and New York. Indeed, the United States is Sanofi's largest market, as indicated by Sanofi's webpage:

21. Defendant Sanofi-Aventis U.S. LLC is a corporation incorporated under the laws of Delaware with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC conducts substantial business in the United States, and specifically in the States of New Jersey and New York. Sanofi-Aventis U.S. LLC has been engaged in the manufacturing, distribution, and sale of defective Zantac in the United States, including in the States of New Jersey and New York.

22. Defendant Sanofi US Services Inc. is a corporation incorporated under the laws of Delaware with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi Services conducts substantial business in the United States, and specifically in the States of New Jersey and New York. Sanofi Services has been engaged in the manufacturing, distribution, and sale of defective Zantac in the United States, including in the States of New Jersey and New York.

23. Sanofi-Aventis and Sanofi Services are wholly owned subsidiaries of Sanofi S.A. There exists, and at all times herein has existed, a unity of ownership between Sanofi S.A., Sanofi-Aventis, Sanofi Services, and their agents such that any individuality or separateness between them has ceased and each of them is the alter ego of the other. Upon information and belief, Sanofi S.A. communicates with Sanofi-Aventis and Sanofi Services concerning virtually all aspects of the Zantac manufactured in the United States. At all relevant times, Sanofi-Aventis and Sanofi Services acted as authorized agents, representatives, servants, employees and/or alter egos of Sanofi S.A. while performing activities including but not limited to advertising, warranties, dissemination of information, and distribution of Zantac medications in the United States and in the States of New Jersey and New York.

JURISDICTION AND VENUE

24. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendants, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

25. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendants Sanofi-Aventis and Sanofi Services have their principal place of business in this District. Venue is further proper in this District pursuant to 28 U.S.C. § 1391(c)(3) with respect to Sanofi S.A. because, as a non-resident of the United States, Sanofi S.A. "may be sued in any judicial district."

CLASS ALLEGATIONS

26. Plaintiff seeks to represent a class defined as all persons in the United States who

purchased Zantac (the "Class"). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendants, Defendants' officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendants and/or Defendants' officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

27. Plaintiff also seeks to represent a subclass of all Class members who purchased Zantac in New York (the "New York Subclass").

28. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class and New York Subclass may be expanded or narrowed by amendment or amended complaint.

29. **Numerosity.** The members of the Class and New York Subclass are geographically dispersed throughout the United States and the State of New York and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of members in the Class and New York Subclass. Although the precise number of Class members is unknown to Plaintiff, the true number of Class and New York Subclass members is known by Defendants and may be determined through discovery. Class and New York Subclass members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendants and third-party retailers and vendors.

30. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Class and New York Subclass and

predominate over any questions affecting only individual Class and New York Subclass members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the Zantac manufactured by Defendants contain dangerously high levels of NDMA, thereby breaching the express and implied warranties made by Defendants and making Zantac unfit for human consumption and therefore unfit for its intended purpose;

(b) whether Defendants knew or should have known that Zantac contained elevated levels of NDMA prior to selling the medication, thereby constituting fraud and/or fraudulent concealment;

(c) whether Defendants have unlawfully converted money from Plaintiff and the Class and New York Subclass;

(d) whether Defendants are liable to Plaintiff and the Class and New York Subclass for unjust enrichment;

(e) whether Defendants are liable to Plaintiff and the Class and New York Subclass for fraudulent concealment;

(f) whether Defendants are liable to Plaintiff and the New York Subclass for violations of New York's consumer-protection laws;

(g) whether Plaintiff and the Class and New York Subclass have sustained monetary loss and the proper measure of that loss;

(h) whether Plaintiff and the Class and New York Subclass are entitled to declaratory and injunctive relief;

(i) whether Plaintiff and the Class and New York Subclass are entitled to restitution and disgorgement from Defendants; and

(j) whether the marketing, advertising, packaging, labeling, and other promotional materials for Zantac are deceptive.

31. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class and New York Subclass in that Defendants mass marketed and sold defective Zantac to consumers throughout the United States. This defect was present in all of the Zantac manufactured by Defendants. Therefore, Defendants breached their express and implied warranties to Plaintiff and Class and New York Subclass members by manufacturing, distributing, and selling the defective Zantac. Plaintiff's claims are typical in that he was uniformly harmed in purchasing and consuming the defective Zantac. Plaintiff's claims are further typical in that Defendants deceived Plaintiff in the very same manner as they deceived each member of the Class and New York Subclass. Further, there are no defenses available to Defendants that are unique to Plaintiff.

32. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Class and New York Subclass. Plaintiff has retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Class and New York Subclass. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class and New York Subclass.

33. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class and New York Subclass members are relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would, thus, be virtually impossible for the Class and New York Subclass, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class and New

York Subclass members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

34. In the alternative, the Class and New York Subclass may also be certified because:

(a) the prosecution of separate actions by individual Class and New York Subclass members would create a risk of inconsistent or varying adjudications with respect to individual Class and New York Subclass members that would establish incompatible standards of conduct for the Defendants;

(b) the prosecution of separate actions by individual Class and New York Subclass members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class and New York Subclass members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendants have acted or refused to act on grounds generally applicable to the Class and New York Subclass as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class and New York Subclass as a whole.

COUNT I
Breach Of Express Warranty
(On Behalf Of The Class And New York Subclass)

35. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

36. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the New York Subclass against Defendants.

37. Plaintiff, and each member of the Class and New York Subclass, formed a contract with Defendants at the time Plaintiff and the other Class and New York Subclass members purchased the defective Zantac. The terms of the contract include the promises and affirmations of fact made by Defendants on Zantac's packaging and through marketing and advertising, including that the product would contain only what was stated on the label, and not harmful impurities such as NDMA. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and New York Subclass and Defendants.

38. Plaintiff relied on the express warranty that his Zantac was safe and would not contain unsafe levels of NDMA. This express warranty further formed the basis of the bargain, and is part of the standardized contract between Plaintiff and the members of the Class and New York Subclass and Defendants.

39. Defendants purport, through their advertising, labeling, marketing and packaging, to create an express warranty that the medication would contain only the ingredients stated on the label, and not harmful impurities such as NDMA.

40. Plaintiff and the Class and New York Subclass performed all conditions precedent to Defendants' liability under this contract when they purchased the defective medication.

41. Defendants breached express warranties about the defective Zantac and its qualities because Defendants' statements about the defective Zantac were false and the defective Zantac does not conform to Defendants' affirmations and promises described above.

42. Plaintiff and each of the members of the Class and New York Subclass would not have purchased the defective Zantac had they known the true nature of the defective Zantac's composition, specifically that Zantac contained elevated levels of NDMA.

43. As a result of Defendants' breaches of express warranty, Plaintiff and each of the members of the Class and New York Subclass have been damaged in the amount of the purchase price of Zantac and any consequential damages resulting from the purchases.

44. On October 22, 2019, prior to filing this action, Defendants were served with a pre-suit notice letter that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiff's counsel sent Defendants a letter advising them that they breached an express warranty and demanded that they cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiff's counsel's letter is attached hereto as Exhibit A.

COUNT II
Breach Of The Implied Warranty Of Merchantability
(On Behalf Of The Class And New York Subclass)

45. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

46. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and the New York Subclass against Defendants.

47. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers, impliedly warranted that Zantac (i) would not contain elevated levels of NDMA and (ii)

is generally recognized as safe for human consumption.

48. Defendants breached the warranty implied in the contract for the sale of the defective Zantac because it could not pass without objection in the trade under the contract description, the Zantac was not of fair or average quality within the description, and the Zantac was unfit for its intended and ordinary purpose because the Zantac manufactured by Defendants was defective in that it contained elevated levels of carcinogenic and liver toxic NDMA, and as such is not generally recognized as safe for human consumption. As a result, Plaintiff and Class and New York Subclass members did not receive the goods as impliedly warranted by Defendants to be merchantable.

49. Plaintiff and Class and New York Subclass members purchased Zantac in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

50. The Zantac was not altered by Plaintiff or Class and New York Subclass members.

51. The Zantac was defective when it left the exclusive control of Defendants.

52. Defendants knew that the Zantac would be purchased and used without additional testing by Plaintiff and Class and New York Subclass members.

53. The defective Zantac was defectively manufactured and unfit for its intended purpose, and Plaintiff and Class and New York Subclass members did not receive the goods as warranted.

54. As a direct and proximate cause of Defendants' breach of the implied warranty, Plaintiff and Class and New York Subclass members have been injured and harmed because: (a) they would not have purchased Zantac on the same terms if they knew that Zantac contained harmful levels of NDMA, and is not generally recognized as safe for human consumption; and

(b) Zantac does not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

COUNT III
Violation Of New York General Business Law § 349
(On Behalf Of The New York Subclass)

55. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

56. Plaintiff brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendants.

57. New York's General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

58. In its sale of goods throughout the State of New York, Defendants conduct business and trade within the meaning and intendment of New York's General Business Law § 349.

59. Plaintiff and members of the New York Subclass are consumers who purchased products from Defendants for their personal use.

60. By the acts and conduct alleged herein, Defendants have engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that Zantac (i) would not contain dangerously high levels of NDMA and (ii) is generally recognized as safe for human consumption.

61. The foregoing deceptive acts and practices were directed at consumers.

62. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of Zantac to induce consumers to purchase the same.

63. By reason of this conduct, Defendants engaged in deceptive conduct in violation of New York's General Business Law.

64. Defendants' actions are the direct, foreseeable, and proximate cause of the damages that Plaintiff and members of the New York Subclass have sustained from having paid for and used Defendants' products.

65. As a result of Defendants' violations, Plaintiff and members of the New York Subclass have suffered damages because: (a) they would not have purchased Zantac on the same terms if they knew that Zantac contained high levels of NDMA; and (b) Zantac does not have the characteristics, uses, benefits, or qualities as promised.

66. On behalf of himself and other members of the New York Subclass, Plaintiff seeks to recover his actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT IV
Violation Of New York General Business Law § 350
(On Behalf Of The New York Subclass)

67. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

68. Plaintiff brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendants.

69. New York's General Business Law § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

70. Pursuant to said statute, false advertising is defined as "advertising, including labeling, of a commodity … if such advertising is misleading in a material respect."

71. Based on the foregoing, Defendants have engaged in consumer-oriented conduct

that is deceptive or misleading in a material way which constitutes false advertising in violation of Section 350 of New York's General Business Law.

72. Defendants' false, misleading, and deceptive statements and representations of fact were and are directed towards consumers.

73. Defendants' false, misleading, and deceptive statements and representations of fact were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

74. Defendants' false, misleading, and deceptive statements and representations of fact have resulted in consumer injury or harm to the public interest.

75. As a result of Defendants' false, misleading, and deceptive statements and representations of fact, Plaintiff and the New York Subclass have suffered and continue to suffer economic injury.

76. As a result of Defendants' violations, Plaintiff and members of the New York Subclass have suffered damages due to said violations because: (a) they would not have purchased Zantac on the same terms if they knew that Zantac contained elevated levels of NDMA and is not safe for human consumption; and (b) Zantac does not have the characteristics, uses, benefits, or qualities as promised.

77. On behalf of himself and other members of the New York Subclass, Plaintiff seeks to recover his actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT V
Unjust Enrichment
(On Behalf Of The Class And New York Subclass)

78. Plaintiff hereby incorporates by reference the allegations contained in all

preceding paragraphs of this complaint.

79. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

80. Plaintiff and the Class and New York Subclass conferred a benefit on Defendants in the form of monies paid to purchase Defendants' defective Zantac.

81. Defendants voluntarily accepted and retained this benefit.

82. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for medications unfit for human use, it would be unjust and inequitable for the Defendants to retain it without paying the value thereof.

COUNT VI
Fraudulent Concealment
(On Behalf Of The Class and New York Subclass)

83. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

84. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

85. Defendants had a duty to disclose material facts to Plaintiff and the Class and New York Subclass given their relationship as contracting parties and intended users of Zantac. Defendants also had a duty to disclose material facts to Plaintiff and the Class and New York Subclass, namely that they were in fact manufacturing, distributing, and selling harmful Zantac unfit for human consumption, because Defendants had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

86. Defendants possessed knowledge of these material facts. In 2003, it was "proposed that elevated levels of NDMA in drinking water…may be associated with the drug

ranitidine."[14] Furthermore, a 2016 study by Stanford University found that individuals who took Zantac had "NDMA levels [in their urine] more than 400 times greater than what the FDA considers acceptable."[15] During that time, Plaintiff and Class and New York Subclass members were using Zantac without knowing it contained dangerous levels of NDMA.

87. Defendants failed to discharge their duty to disclose these materials facts.

88. In so failing to disclose these material facts to Plaintiff and the Class and New York Subclass, Defendants intended to hide from Plaintiff and the Class and New York Subclass that they were purchasing and consuming Zantac with harmful defects that was unfit for human use, and thus acted with scienter and/or an intent to defraud.

89. Plaintiff and the Class and New York Subclass reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the defective Zantac manufactured sold by Defendants had they known it contained unsafe levels of NDMA.

90. As a direct and proximate cause of Defendants' fraudulent concealment, Plaintiff and the Class and New York Subclass suffered damages in the amount of monies paid for the defective Zantac.

91. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VII
Fraud
(On Behalf Of The Class and New York Subclass)

92. Plaintiff hereby incorporates by reference the allegations contained in all

[14] VALISURE PETITION at 4-5.
[15] Jonathan Lapook, *Potentially Dangerous Chemical Found in Popular Heartburn Pill Zantac*, CBS NEWS, Oct. 8, 2019, https://www.cbsnews.com/news/zantac-ndma-levels-potentially-dangerous-chemical-zantac-ranitidine-heartburn-pills-2019-10-08/.

preceding paragraphs of this complaint.

93. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

94. As discussed above, Defendants provided Plaintiff and Class and New York Subclass members with materially false or misleading information about the Zantac manufactured by Defendants. Specifically, Defendants have marketed Zantac as safe for human consumption. As indicated above, however, these representations are false and misleading as Defendants' Zantac medications contained elevated levels of NDMA.

95. The misrepresentations and omissions of material fact made by Defendants, upon which Plaintiff and Class and New York Subclass members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class and New York Subclass members to purchase defective Zantac.

96. Defendants knew that Zantac was contaminated with this harmful impurity, but continued to manufacture it nonetheless. In 2003, it was "proposed that elevated levels of NDMA in drinking water … may be associated with the drug ranitidine."[16] Furthermore, a 2016 study by Stanford University found that individuals who took Zantac had "NDMA levels [in their urine] more than 400 times greater than what the FDA considers acceptable."[17] During that time, Plaintiff and Class and New York Subclass members were using the medication without knowing it contained dangerous levels of NDMA.

97. The fraudulent actions of Defendants caused damage to Plaintiff and Class and

[16] VALISURE PETITION at 4-5.
[17] Jonathan Lapook, *Potentially Dangerous Chemical Found in Popular Heartburn Pill Zantac*, CBS NEWS, Oct. 8, 2019, https://www.cbsnews.com/news/zantac-ndma-levels-potentially-dangerous-chemical-zantac-ranitidine-heartburn-pills-2019-10-08/.

New York Subclass members, who are entitled to damages and other legal and equitable relief as a result.

98. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VIII
Conversion
(On Behalf Of The Class And New York Subclass)

99. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

100. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and New York Subclass against Defendants.

101. Plaintiff and the Class and New York Subclass have an ownership right to the monies paid for the defective Zantac manufactured by Defendants.

102. Defendants have wrongly asserted dominion over the payments illegally diverted to them for the defective Zantac. Defendants have done so every time that Plaintiff and the Class and New York Subclass bought Zantac over the counter.

103. As a direct and proximate cause of Defendants' conversion, Plaintiff and the Class and New York Subclass suffered damages in the amount of the payments made for each time they bought Zantac over the counter.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendants, as follows:

A. For an order certifying the nationwide Class and the New York Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff as the representative for the Class and New York Subclass and Plaintiff's attorneys as Class Counsel;

B. For an order declaring the Defendants' conduct violates the statutes referenced herein;

C. For an order finding in favor of Plaintiff, the nationwide Class, and the New York Subclass on all counts asserted herein;

D. For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

E. For prejudgment interest on all amounts awarded;

F. For an order of restitution and all other forms of equitable monetary relief;

G. For injunctive relief as pleaded or as the Court may deem proper; and

H. For an order awarding Plaintiff and the Class and New York Subclass their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable of right.

Dated: October 24, 2019

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ Andrew J. Obergfell*
Andrew J. Obergfell

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EXHIBIT A

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October 22, 2019

Via Certified Mail – Return Receipt Requested

Sanofi-Aventis U.S. LLC
55 Corporate Drive
Bridgewater, New Jersey 08807

Sanofi U.S. Services Inc.
55 Corporate Drive
Bridgewater, New Jersey 08807

Re: Notice and Demand Letter Pursuant to U.C.C. § 2-607; New York's General Business Law §§ 349-350; and all other relevant state and local laws

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by Sanofi-Aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, "Sanofi") pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranties – and violations of state consumer protection laws – related to our client, Alfonso Pinales, and a class of all similarly situated purchasers (the "Class") of defective Zantac manufactured by Sanofi.

Our client purchased Zantac, a medication containing ranitidine, manufactured by Sanofi, in New York. Our client's Zantac was defective in that it contained elevated levels of N-nitrosodimethylamine ("NDMA"), a carcinogenic and liver-damaging impurity. On September 13, 2019, the U.S. Food & Drug Administration ("FDA") announced the presence of NDMA in ranitidine medications, including Zantac. The FDA has since found unacceptable levels of NDMA in samples of ranitidine. In short, the Zantac medications that our client and the Class purchased are worthless, as they contain NDMA, rendering them unusable and unfit for human consumption. Sanofi violated express and implied warranties made to our client and the Class regarding the quality and safety of the Zantac they purchased. *See* U.C.C. §§ 2-313, 2-314.

Additionally, this letter also serves as notice of violation of New York General Business Law §§ 349 and 350, and all other relevant state and local laws. As a result of Sanofi's violation of New York General Business Law § 349 and § 350, Mr. Pinales sustained injury.

On behalf of our client and the Class, we hereby demand that Sanofi immediately (1) cease and desist from continuing to sell defective Zantac and (2) make full restitution to all purchasers of the defective Zantac of all purchase money obtained from sales thereof.

We also demand that Sanofi preserve all documents and other evidence which refers or relates to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the packaging, labeling, and manufacturing process for Sanofi's Zantac;

2. All documents concerning the design, development, supply, production, extraction, and/or testing of Zantac manufactured by Sanofi;

3. All tests of Zantac manufactured by Sanofi;

4. All documents concerning the pricing, advertising, marketing, and/or sale of Zantac manufactured by Sanofi;

5. All communications with customers involving complaints or comments concerning the Zantac manufactured by Sanofi;

6. All documents concerning communications with any retailer involved in the marketing or sale of Zantac manufactured by Sanofi;

7. All documents concerning communications with federal or state regulators; and

8. All documents concerning the total revenue derived from sales of Zantac.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,

Andrew J. Obergfell

Andrew J. Obergfell